U.S. Department of Energy
Washington, D.C.

ORDER

DRAFT
DOE O 414.1B

Approved: XX-XX-04
Review Date: XX-XX-XX

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SUBJECT: QUALITY ASSURANCE

1. OBJECTIVES.

   a. To ensure that the quality of Department of Energy (DOE)/National Nuclear Security Administration (NNSA), products and services meet or exceed the customers' expectations.

   b. To achieve quality assurance (QA) for all work based upon the following principles:

      (1) That quality is assured and maintained through a single, integrated, effective quality assurance program (i.e., management system).

      (2) That management support for planning, organization, resources, direction, and control is essential to QA.

      (3) That performance and quality improvement require thorough, rigorous assessment and corrective action.

      (4) That the performers of work are responsible for achieving and maintaining quality.

      (5) That environmental, safety, and health risks and impacts of work are minimized while maximizing reliability and performance of work products.

   c. To establish quality process requirements to be implemented under a QA Program for the control of suspect/counterfeit items and safety issue corrective actions.

2. CANCELLATIONS. This Order cancels the following.

   a. DOE O 414.1A, *Quality Assurance*, dated 9-29-99.

   b. DOE O 440.1A, *Worker Protection Management for DOE Federal and Contractor Employees,* dated 3-27-98, portions as follows:

      (1) Attachment 1, paragraph 8, Suspect and Counterfeit Item (S/CI) Controls, and

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Deleted: [NOTE: Attachment 2, Safety Issue Corrective Action Process—Supplemental Quality Requirements for DOE Elements, has been moved to (draft) DOE M 414.1-1, Corrective Action Management Program, dated XX-XX-03.]

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All Departmental Elements

INITIATED BY:
Office of Environment, Safety and Health

(2) Attachment 2, paragraph 22, Suspect and Counterfeit Item (S/CI) Controls.

c. Cancellation of an Order does not, by itself, modify or otherwise affect any contractual obligation to comply with the Order. Canceled Orders that are incorporated by reference in a contract must remain in effect until the contract is modified to delete the requirements in the canceled Orders.

3. APPLICABILITY.

a. DOE Elements. Except for the exclusions in paragraph 3c, this Order applies to all DOE/NNSA elements (see Attachment 1).

This Order includes a requirement to integrate multiple QA Program drivers imposed by QA regulations of the DOE (10 CFR 830), the U.S. Nuclear Regulatory Commission, and other Federal agencies. The Order includes supplemental activity-specific requirements for work that may also need to comply with those QA regulations. This integration requirement supplements but does not supersede or alter compliance with any QA regulations. [Note: See QAP integration requirement, paragraph 4a(4).]

b. Site/Facility Management Contractors.

(1) Except for the exclusions in paragraph 3c, the Contractor Requirements Document (CRD), Attachment 2, sets forth requirements of this Order that will apply to site/facility management contractors whose contracts include the CRD.

(2) This CRD must be included in site/facility management contracts that require or involve responsibility for work or operations at DOE sites or facilities. This includes work that may take place outside the physical boundaries of a DOE facility, such as design or analysis services.

(3) This Order does not automatically apply to other than site/facility management contractors.

(4) Secretarial Officers (SOs) are responsible for notifying contracting officers which site/facility management contractors are affected by this Order. Once notified, contracting officers are responsible for incorporating the CRD into the contracts of affected site/facility management contractors via the laws, regulations and DOE directives clause of the contracts.

(5) As the laws, regulations, and DOE directives clause of site/facility management contract states, regardless of the performer of the work, site/facility management contractor with the CRD incorporated into its contract is responsible for compliance with the requirements of the CRD.

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(a) An affected site/facility management contractor are is responsible for flowing down the requirements of this CRD to subcontractors at any tier to the extent necessary to ensure the site/facility management contractors' compliance with the requirements.

(b) In doing so, the contractor shall not unnecessarily or imprudently flow down requirements to subcontracts. That is, the contractor shall both—

1 ensure that it and its subcontractors comply with the requirements of the CRD to the extent necessary to ensure the contractor's compliance and

2 incur only costs that would be incurred by a prudent person in the conduct of competitive business.

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c. Exclusions.

(1) This Order does not apply to the DOE/NNSA Naval Reactors Program in accordance with Executive Order 12344, statutorily prescribed by Public Law 98-525 [42 United States Code (U.S.C.) 7158, note].

(2) This Order does not apply to the Bonneville Power Administration (BPA), in accordance with Secretarial delegation Order Number 00-033.00A, dated 9/27/2002, to the BPA Administrator and Chief Executive Officer.

Deleted: This Order does not apply to any work that is subject to the requirements imposed by QA regulations of DOE, the U.S. Nuclear Regulatory Commission, or any other Federal agency. Work that may be subject to QA regulations and the requirements of this Order should be integrated and made consistent with all requirements. [See QAP integration requirement, paragraph 4a(4).]

4. REQUIREMENTS.

a. Quality Assurance Program (QAP) Requirements. Each DOE element must develop and implement a QAP that—

(1) Implements quality assurance criteria as defined in paragraph 4b, using a graded approach and describes how the criteria are applied. (Note: See paragraph 6, for compliance references.)

(2) Uses the appropriate voluntary national or international consensus standard (or later revision) where practicable and consistent with contractual or regulatory requirements, and identifies the standard used as follows.

(a) ASME NQA-1-2000, Quality Assurance Requirements for Nuclear Facility Applications (for nuclear-related activities);

(b) ANSI/ISO/ASQ Q 9001-2000, *Quality Management System - Requirements* (for non-nuclear activities);

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(c) ANSI/ASQ Z 1.13, *Quality Guidelines for Research,* 1999, (for non-nuclear research activities).

(3) Applies additional standards, where practicable and consistent with contractual or regulatory requirements, necessary to address unique/specific work activities (e.g., development and use of safety software or establishing competence of a testing and calibration laboratory).

(4) Integrates the quality management system requirements, suspect/counterfeit items prevention process (see Attachment 3), and the Corrective Action Management Program (see Attachment 4) as defined in this Order; and other quality or management system requirements in DOE directives and external requirements, including as applicable—

(a) DOE P 450.4, *Safety Management System Policy,* dated 10-15-96;

(b) DOE P 450.5, *Line Environment, Safety and Health Oversight,* dated 06-26-97;

(c) NNSA *Quality Management Policy*, QC-1, (quality management system for the nuclear weapons complex and weapons-related activities);

(d) DOE Office of Civilian Radioactive Waste Management, *Quality Assurance Requirements and Description*, RW-0333P;

(e) DOE Carlsbad Field Office, *Quality Assurance Program Description*, DOE/CBFO-94-1012, (for the Waste Isolation Pilot Plant and related activities); and,

Note: This integration requirement does not establish or imply a hierarchy of quality requirements or programs.

b. Quality Assurance Criteria. The QAP must address the following management, performance, and assessment criteria.

(1) Management/Criterion 1—Program.

(a) Establish an organizational structure, functional responsibilities, levels of authority, and interfaces for those managing, performing, and assessing the work.

(b) Establish management processes, including planning, scheduling, and providing resources for the work.

(2) Management/Criterion 2—Personnel Training and Qualification.

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(a) Train and qualify personnel to be capable of performing their assigned work.

(b) Provide continuing training to personnel to maintain their job proficiency.

(3) Management/Criterion 3—Quality Improvement.

(a) Establish and implement processes to detect and prevent quality problems.

(b) Identify, control and correct items, services, and processes that do not meet established requirements.

(c) Identify the causes of problems and work to prevent recurrence as a part of correcting the problem.

(d) Review item characteristics, process implementation, and other quality-related information to identify items, services, and processes needing improvement.

(4) Management/Criterion 4—Documents and Records.

(a) Prepare, review, approve, issue, use, and revise documents to prescribe processes, specify requirements, or establish design.

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(b) Specify, prepare, review, approve, and maintain records.

(5) Performance/Criterion 5—Work Processes.

(a) Perform work consistent with technical standards, administrative controls, and other hazard controls adopted to meet regulatory or contract requirements using approved instructions, procedures, or other appropriate means.

(b) Identify and control items to ensure their proper use.

(c) Maintain items to prevent their damage, loss, or deterioration.

(d) Calibrate and maintain equipment used for process monitoring or data collection.

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(6) Performance/Criterion 6—Design.

(a) Design items and processes using sound engineering/scientific principles and appropriate standards.

(b) Incorporate applicable requirements and design bases in design work and design changes.

(c) Identify and control design interfaces.

(d) Verify or validate the adequacy of design products using individuals or groups other than those who performed the work.

(e) Verify or and validate work before approval and implementation of the design.

(7) Performance/Criterion 7—Procurement.

(a) Procure items and services that meet established requirements and perform as specified.

(b) Evaluate and select prospective suppliers on the basis of specified criteria.

(c) Establish and implement processes to ensure that approved suppliers continue to provide acceptable items and services.

(8) Performance/Criterion 8—Inspection and Acceptance Testing.

(a) Inspect and test specified items, services, and processes using established acceptance and performance criteria.

(b) Calibrate and maintain equipment used for inspections and tests.

(9) Assessment/Criterion 9—Management Assessment. Ensure managers assess their management processes and identify and correct problems that hinder the organization from achieving its objectives.

(10) Assessment/Criterion 10—Independent Assessment.

(a) Plan and conduct independent assessments to measure item and service quality, to measure the adequacy of work performance, and to promote improvement.

(b) Establish sufficient authority, and freedom from line management for the group performing independent assessments.

(c) Ensure persons conducting independent assessments are technically qualified and knowledgeable in the areas to be assessed.

5. RESPONSIBILITIES. QAP implementation, assessment, and improvement are senior management responsibilities.

a. Deputy Secretary. Provides leadership for QA implementation issues and quality problem resolution with the support of the Office of Environment, Safety and Health.

b. Secretarial Officers.

(1) Ensure that Headquarters, field elements, and contractors implement requirements of this Order in an integrated manner and coordinate the resolution of quality issues among these organizations.

(2) Develop, approve, and implement QAPs governing the work of their organizations, including safety software development/use, in accordance with the requirements defined in paragraph 4 of this Order and in Attachment 3, Suspect/Counterfeit Items Prevention Program. Identify senior management positions specifically assigned this responsibility.

(3) Provide direction and resources for implementing the requirements for work within their purview.

(4) Review and approve field element QAPs. The scope and rigor of a review must be graded according to the status of prior quality performance and any third-party QAP certification.

(5) Review and approve new and revised field element and contractor QAPs within their purview or delegate this authority to the field element manager. The scope and rigor of a review must be graded according to the status of prior quality performance and any third-party QAP certification.

(6) Review, resolve differences of opinion, and approve or reject QAPs within 90 days of receipt.

(7) Report management assessment results periodically to the Deputy Secretary (through the Under Secretary) describing the effectiveness of QA implementation.

(8) Direct contracting officers to specify—

(a) each procurement requiring application of the CRD to this Order (Attachment 2) and 10 CFR 830 Subpart A,

(b) requirements for flow down of provisions of the CRD to subcontractors or subawards, and

(c) provisions of the CRD with which contractors or subcontractors are to comply.

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(9) Approve Corrective Action Management Program (CAMP) Corrective Action Plans (CAPs) developed by the FEM within 60 calendar days from the date the assessment report was issued.

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c. Field Element[1] Managers.

(1) Develop and implement approved QAPs governing the work under their purview, including software development/use, in accordance with requirements of this Order (see paragraph 4 and Attachment 3), and identify senior management positions assigned this responsibility.

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(2) Submit QAPs to the appropriate SOs for review, resolution of differences of opinion, and approval.

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(3) Review, and where delegated authority to do so approve, new and revised QAPs for contractors within their purview. The scope and rigor of review must be graded based on the status of the contractor's prior quality performance and any third-party QAP certification. QAPs must be reviewed and approved—or rejected—within 90 days of receipt.

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(4) Perform independent assessments of contractor organizations to evaluate the adequacy and effective implementation of their QAPs. The frequency and scope of assessments must be graded based on the status of prior quality performance and any third-party QAP certification. Other suitable methods may be used in combination with independent assessments.

(5) Periodically report management assessment results to their organizations' SOs describing the effectiveness of the field element and contractor QA implementation.

(6) Prepare and implement a CAP to address all findings in the CAMP assessment report; and enter, track, and report the status of the CAP in the Corrective Action Tracking System (CATS).

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(7) Complete the CAP and conduct follow up review on the effectiveness of the corrective actions in resolving and preventing recurrence of all findings. Approve the effectiveness review report and follow up report recommendations.

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d. Contracting Officers. Apply provisions of the CRD to contracts falling within the scope of this Order, as directed by the SO. Incorporate the provisions in procurement and contract documents in time for the contractors to comply with the requirements.

[1]Operations offices, service centers, site offices, area offices, and regional offices of federally staffed laboratories.

e. Assistant Secretary for Environment, Safety and Health. Acts as DOE's independent element responsible for safety aspects relative to public and worker health and safety and environmental protection. The Assistant Secretary has the following quality assurance responsibilities in addition to SO duties prescribed in paragraph 5b.

(1) Quality Policy.

(a) Develops and maintains QA policy, requirements (including the QA Rule), guides, and standards for all DOE work.

(b) Provides advice and assistance (including QAP reviews) to DOE elements and contractors concerning implementation of this Order.

(c) Is a central point of contact for coordination within DOE and liaison with other agencies and groups for the development of QA policy, requirements, guides, and standards.

(d) Reviews proposed statutes, regulations, standards, DOE directives, and DNFSB documents for applicability to and potential impact on DOE quality programs.

(2) Quality Program Support.

(a) Identifies and proposes resolutions for crosscutting QA issues within the Department to improve implementation.

(b) Submits a periodic update to the Deputy Secretary on the effectiveness of QA policy implementation across the Department.

(c) Manages the DOE Corrective Action Management Program in accordance with Attachment 4.

(d) Manages the DOE Suspect/Counterfeit Items Prevention Process in accordance with Attachment 3.

(e) Manages the DOE Safety Software Quality Program.

(3) CAMP and CATS.

(a) Manages the CAMP, and develops and maintains CAMP policies, procedures and guidelines.

(b) Maintains CATS and assists FEMs in accessing and editing CAP data. Maintains a CAMP website providing background and information on the program.

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(c) Coordinates status and maintenance of the CAMP with SOs, FEMs, and assessing organizations, including periodic reports on program status.

(d) Sponsors and co chairs the DOE Corrective Action Management (CAM) Team.

f. Director, Office of Independent Oversight and Performance Assurance.

(1) Conducts various independent assessments of SO, field element, and contractor implementation of this Order (ref. DOE Order O 470.2B).

(2) Includes in assessments all aspects of QA related to environment, safety, health, safeguards, and security.

(3) Reports assessment results to the appropriate Under Secretary of Energy, Assistant Secretary for Environment, Safety and Health, and the assessed organization.

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6. REFERENCES. The following provide guidance and responsibilities for implementing this Order.

a. DOE G 414.1-2A, *Quality Assurance Management System Guide for Use with 10 CFR 830.120 and DOE O 414.1,* dated 6-17-99.

b. DOE G 414.1-1A, *Implementation Guide for Use with Management Assessment and Independent Assessment Guide for Use With 10 CFR 830.120 and DOE 5700.6c, Quality Assurance; DOE P 450.4, Safety Management System Policy; DOE P 450.5, Line ES&H Oversight Policy*, dated 5-31-01.

c. DOE G 440.1-6, *Implementation Guide for Use with Suspect/Counterfeit Items Requirements of DOE O 440.1, Worker Protection Management*; 10 CFR 830.120; and DOE 5700.6c, *Quality Assurance*, dated 6-30-97 (Revision in process to be released as G 414.1-3).

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d. DOE M 411.1-1C, *Safety Management Functions, Responsibilities, and Authorities Manual,* dated 12-31-03.

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e. *Quality Assurance Standards for Safety Software in Department of Energy Nuclear Facilities*, dated 9-30-03 (http://tis.eh.doe.gov/techstds/toolsframe.html).

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7. DEFINITIONS.

a. Assessment. The act of reviewing, evaluating, inspecting, testing, checking, surveillance, auditing, or otherwise determining and documenting whether items, processes, systems, or services meet specified requirements and are performing effectively.

b. Graded Approach. The process by which the level of detail in analyses, documentation, and actions necessary to comply with requirements is commensurate with—

(1) the relative importance to safety, safeguards, and security;

(2) the magnitude of any hazard involved;

(3) the life-cycle stage of a facility;

(4) the programmatic mission of a facility;

(5) the particular characteristics of a facility;

(6) any other relevant factors.

c. Item. An all-inclusive term used in place of any of the following: appurtenance, assembly, component, equipment, material, module, part, structure, product, software, subassembly, subsystem, system, unit, or support systems.

d. Process. A series of actions that achieves an end result.

e. Quality. The condition achieved when an item, service, or process meets or exceeds the user's requirements and expectations.

f. Quality Assurance. All those actions that provide confidence that quality is achieved.

g. Quality Assurance Program. The overall program (management system) established to assign responsibilities and authorities, define policies and requirements, and provide for the performance and assessment of work.

h. Safety. An all-inclusive term used synonymously with environment, safety, and health to encompass protection of the public, the workers, and the environment.

i. Safety Software. Includes both safety system safety analysis and design software.

(1) Safety System Software. Computer software and firmware that performs a safety system function as part of a structure, system, or component (SSC) that has been functionally classified as Safety Class (SC) or Safety Significant (SS). This also includes computer software such as human-machine interface software, network interface software, programmable logic controller (PLC) programming language software, and safety management databases that are not part of an SSC but whose operation or malfunction can directly affect SS and SC SSC function (ref. 10 CFR 830.2).

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(2) Safety Analysis and Design Software. Computer software that is not part of a structure, system, or component (SSC) but is used in the safety classification, design, and analysis of nuclear facilities to ensure the proper accident analysis of nuclear facilities; the proper analysis and design of safety SSCs; and, the proper identification, maintenance, and operation of safety SSCs.

j. Service. The performance of work, such as design, construction, fabrication, decontamination, environmental remediation, waste management, laboratory sample analysis, safety system software development/validation/testing, inspection, nondestructive examination/testing, environmental qualification, equipment qualification, training , assessment, repair, installation, or the like. Formatted: Bullets and Numbering

k. Suspect/Counterfeit Items (S/CI). An item is suspect when visual inspection or testing indicates it may not conform to established Government or industry-accepted specifications or national consensus standards, or whose documentation, appearance, performance, material, or other characteristics may have been misrepresented b the supplier or manufacturer. A counterfeit item is one that has been copied or substituted without legal right or authority to do so or one whose material, performance, or characteristics have been misrepresented by the supplier or manufacturer. Item that do not conform to established requirements are not normally considered S/CIs if nonconformity results from one or more of the following conditions (which must be controlled by site procedures as nonconforming items): Formatted: Bullets and Numbering Deleted: should

(1) defects resulting from inadequate design or production quality control;

(2) damage during shipping, handling, or storage;

(3) improper installation; deterioration during service;

(4) degradation during removal;

(5) failure resulting from aging or misapplication; or

(6) other controllable causes.

l. Work. Performing a defined task or activity such as research and development, operations, environmental remediation, maintenance and repair, administration, safety software development/validation/testing and use, inspection, safeguards and security, data collection and analysis. Formatted: Bullets and Numbering

8. CONTACT. Address questions concerning this Order to Office of Quality Assurance Programs, 301-903-2954.

BY ORDER OF THE SECRETARY OF ENERGY:

KYLE E. McSLARROW
Deputy Secretary

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DOE ORGANIZATIONS TO WHICH DOE O 414.1B IS APPLICABLE

This Notice is applicable to the following DOE organizations and their associated Federal field elements:

Office of the Chief Information Officer
Office of Civilian Radioactive Waste Management
Office of Congressional and Intergovernmental Affairs
Office of Counterintelligence
Departmental Representative to the Defense Nuclear Facilities Safety Board
Office of Economic Impact and Diversity
Office of Electric Transmission and Distribution
Office of Energy Assurance
Office of Energy Efficiency and Renewable Energy
Energy Information Administration
Office of Environment, Safety and Health
Office of Environmental Management
Office of Fossil Energy
Office of General Counsel
Office of Hearings and Appeals
Office of Independent Oversight and Performance Assurance
Office of the Inspector General
Office of Intelligence
Office of Legacy Management
Office of Management, Budget and Evaluation and Chief Financial Officer
National Nuclear Security Administration
Office of Nuclear Energy, Science and Technology
Office of Policy and International Affairs
Office of Public Affairs
Office of Science
Office of Security
Office of Security and Safety Performance Assurance
Office of Worker and Community Transition

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Southwestern Power Administration
Western Area Power Administration

CONTRACTOR REQUIREMENTS DOCUMENT

DOE O 414.1B, *Quality Assurance*

This Contractor Requirements Document (CRD) establishes the requirements for Department of Energy (DOE)/National Nuclear Security Administration (NNSA) contractors, with responsibility for work or operations at DOE sites or facilities. This includes work that may take place outside the physical boundaries of a DOE facility or work performed by suppliers and subcontractors in support of operations. Contractors conducting activities or providing items or services that affect, or may affect, the safety of DOE nuclear facilities must conduct work in accordance with the QA requirements of 10 CFR 830 Subpart A.

This CRD includes a requirement to integrate multiple QA Program drivers imposed by QA regulations of the DOE (10 CFR 830), the U.S. Nuclear Regulatory Commission, and other Federal agencies. The CRD includes supplemental activity-specific requirements for work that may also need to comply with those QA regulations. This integration requirement supplements but does not supersede or alter compliance any QA regulations. [Note: See QAP integration requirement, paragraph 2a(2).] Regardless of the performer of the work, the contractor is responsible for complying with the requirements of this CRD. The contractor is responsible for flowing down the requirements of this CRD to subcontractors at any tier to the extent necessary to ensure the contractor's compliance with the requirements. In doing so, the contractor must not unnecessarily or imprudently flow down requirements to subcontracts. That is, the contractor will ensure (1) that it and its subcontractors comply with the requirements of this CRD to the extent necessary to ensure the contractor's compliance and (2) only incur costs that would be incurred by a prudent person in the conduct of competitive business.

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1. OBJECTIVES.

   a. To ensure that the quality of Department of Energy (DOE)/National Nuclear Security Administration (NNSA), products and services meet or exceed the customers' expectations.

   b. To achieve quality assurance (QA) for all work based upon the following principles:

      (1) That quality is assured and maintained through a single, integrated, effective quality assurance program (i.e., management system).

      (2) That management support for planning, organization, resources, direction, and control is essential to QA.

      (3) That performance and quality improvement require thorough, rigorous assessment and corrective action.

(4) That the performers of work are responsible for achieving and maintaining quality.

(5) That environmental, safety, and health risks and impacts of work are minimized while maximizing reliability and performance of work products.

c. To establish quality process requirements to be implemented under a QA Program for the control of suspect/counterfeit items.

2. GENERAL QUALITY REQUIREMENTS.

a. Quality Assurance Program Development and Implementation. A contractor must assign and identify a senior management position responsible for the development, implementation, assessment, and improvement of a quality assurance program (QAP). The contractor must develop and implement a QAP that—

(1) Implements the quality assurance (QA) criteria as defined in paragraph 3 of this CRD and suspect/counterfeit items (S/CI) prevention requirements as defined in paragraph 4 using a graded approach, and describing how QA criteria and graded approach are applied. [Note: See references in paragraph 2c of this CRD for guidance on compliance.]

(2) Uses the appropriate voluntary national or international consensus standard (or later revision) where practicable and consistent with contractual or regulatory requirements and identifies the standard used as follows.

(a) ASME NQA-1-2000, *Quality Assurance Requirements for Nuclear Facility Applications* (for nuclear-related activities);

(b) ANSI/ISO/ASQ Q 9001-2000, *Quality Management System - Requirements* (for non-nuclear activities);

(c) ANSI/ASQ Z 1.13, 1999, *Quality Guidelines for Research, (*for non-nuclear research activities);

(3) Applies additional standards, where practicable and consistent with contractual or regulatory requirements, necessary to address unique/specific work activities (e.g., development and use of safety software or the competence of a testing and calibration laboratory).

(4) Integrates quality or management system requirements as defined in this CRD with DOE directives and similar external requirements including as applicable:

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(a) DOE P 450.4, *Safety Management System Policy,* dated 10-15-96;

(b) DOE P 450.5, *Line Environment, Safety and Health Oversight,* dated 06-26-97;

(c) NNSA *Quality Management Policy*, QC-1, (quality management system for the nuclear weapons complex and weapons-related activities);

(d) DOE Office of Civilian Radioactive Waste Management, *Quality Assurance Requirements and Description*, RW-0333P;

(e) DOE Carlsbad Field Office, *Quality Assurance Program Description*, DOE/CBFO-94-1012, (for the Waste Isolation Pilot Plant and related activities); and,

(f) Other applicable quality management system requirements.

Note: This integration requirement does not establish or imply a hierarchy of quality requirements or programs.

(5) Before beginning work under a DOE contract, submits a QAP plan to DOE for approval as specified and implement the QAP as approved and modified by DOE. In the submittal, indicate any third-party QAP certification and the basis for that certification.

(a) QAPs approved in accordance with DOE O 414.1A, *Quality Assurance*, dated 9-29-99, must be revised to address enhancements required by this CRD.

(b) Contractors will regard their QAPs as approved by DOE 90 days after DOE receipt, unless approved or rejected by DOE at an earlier date, and must include any modification made or directed by DOE.

b. Quality Assurance Program Changes. A contractor may make changes to an approved QAP at any time.

(1) Changes made over the previous year must be submitted annually to DOE for review and approval.

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(2) In the submittal, identify the changes, the reason for the changes, and the basis for concluding that the revised QAP continues to satisfy the requirements of this CRD.

Note: Changes made to correct spelling, punctuation, or other editorial items do not require explanation.

c. Quality Guidance Usage. The contractor must consider the guidance on quality assurance provided by the latest revision of the documents listed below in developing and implementing their QAP.

(1) DOE G 414.1-2A, *Quality Assurance Management System Guide for Use with 10 CFR 830.120 and DOE O 414.1*, dated 6-17-99;

(2) DOE G 414.1-1A, *Implementation Guide for Use with Independent and Management Assessment Requirements of 10 CFR 830.120 and DOE 5700.6c, Quality Assurance DOE P 450.4, Safety Management System Policy; DOE P 450.5, Line ES&H Oversight Policy,* dated 5-31-01;

(3) DOE G 440.1-6, *Implementation Guide for Use with Suspect/Counterfeit Items Requirements of DOE O 440.1, Worker Protection Management; 10 CFR 830.120; and DOE 5700.6c, Quality Assurance,* dated 6-30-97 [Note: This Guide currently in revision to be released as G 414.1-3];

3. QUALITY ASSURANCE CRITERIA. The QAP must address the following management, performance, and assessment criteria.

a. Management/Criterion 1—Program.

(1) Establish an organizational structure, functional responsibilities, levels of authority, and interfaces for those managing, performing, and assessing the work.

(2) Establish management processes, including planning, scheduling, and providing resources for the work.

b. Management/Criterion 2—Personnel Training and Qualification.

(1) Train and qualify personnel to be capable of performing their assigned work.

(2) Provide continuing training to personnel to maintain their job proficiency.

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(Draft) DOE M 414.1-1, *Corrective Action Management Program Manual,* dated XX-XX-03.

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c. Management/Criterion 3—Quality Improvement.

(1) Establish and implement processes to detect and prevent quality problems.

(2) Identify, control and correct items, services, and processes that do not meet established requirements.

(3) Identify the causes of problems and work to prevent recurrence as a part of correcting the problem.

(4) Review item characteristics, process implementation, and other quality-related information to identify items, services, and processes needing improvement.

d. Management/Criterion 4—Documents and Records.

(1) Prepare, review, approve, issue, use, and revise documents to prescribe processes, specify requirements, or establish design.

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(2) Specify, prepare, review, approve, and maintain records.

e. Performance/Criterion 5—Work Processes.

(1) Perform work consistent with technical standards, administrative controls, and other hazard controls adopted to meet regulatory or contract requirements using approved instructions, procedures, or other appropriate means.

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(2) Identify and control items to ensure their proper use.

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(3) Maintain items to prevent their damage, loss, or deterioration.

(4) Calibrate and maintain equipment used for process monitoring or data collection.

f. Performance/Criterion 6—Design.

(1) Design items and processes using sound engineering/scientific principles and appropriate standards.

(2) Incorporate applicable requirements and design bases in design work and design changes.

(3) Identify and control design interfaces.

(4) Verify or validate the adequacy of design products using individuals or groups other than those who performed the work.

(5) Verify or and validate work before approval and implementation of the design.

g. Performance/Criterion 7—Procurement.

(1) Procure items and services that meet established requirements and perform as specified.

(2) Evaluate and select prospective suppliers on the basis of specified criteria.

(3) Establish and implement processes to ensure that approved suppliers continue to provide acceptable items and services.

h. Performance/Criterion 8—Inspection and Acceptance Testing.

(1) Inspect and test specified items, services, and processes using established acceptance and performance criteria.

(2) Calibrate and maintain equipment used for inspections and tests.

i. Assessment/Criterion 9—Management Assessment. Ensure managers assess their management processes and identify and correct problems that hinder the organization from achieving its objectives.

j. Assessment/Criterion 10—Independent Assessment.

(1) Plan and conduct independent assessments to measure item and service quality, to measure the adequacy of work performance, and to promote improvement.

(2) Establish sufficient authority, and freedom from line management, for the group performing independent assessments.

(3) Ensure persons conducting independent assessments are technically qualified and knowledgeable in the areas to be assessed.

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4. DOE-WIDE SUSPECT/COUNTERFEIT ITEMS (S/CI) PREVENTION PROCESS. A DOE-wide S/CI prevention process is operated by the DOE Office of Environment, Safety and Health as a service to DOE and its contractors, and provides for: collection, analysis, and dissemination of S/CI information; notification of Secretarial Officers (SOs) when specific actions must be taken to investigate and resolve S/CI quality and safety issues; and, tracking and reporting the status of corrective actions.

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Note: This service does not relieve the contractor from complying with the following requirements for their scope of work.

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a. Supplemental Quality Management System Requirements for S/CIs. An S/CI prevention process must be developed and implemented as a part of the contractor's QAP commensurate with the facility/activity hazards and mission impact. The QAP must be applied to identifying and analyzing SC/Is, removing them, and preventing SC/Is from being supplied to DOE/NNSA and its contractors. The QAP must address the following elements for S/CI prevention:

(1) preventing the introduction and use of S/CIs through engineering involvement, design, procurement, testing, inspection, maintenance, evaluation, disposition, reporting, trend analysis, and lessons learned work process controls;

(2) training and informing managers, supervisors, and workers on S/CI processes and controls (including prevention, detection, and disposition of S/CIs);

(3) identifying and disposing of S/CIs on site;

(4) permitting the use an S/CI only when it has been found acceptable through engineering analysis and formal disposition process;

(5) collecting, maintaining, disseminating, and using the most accurate, up-to-date information on S/CIs and associated suppliers using all available sources including the:

(a) Government Industry Data Exchange Program;

(b) Institute of Nuclear Power Operators;

(c) DOE Occurrence Reporting and Processing System; and,

(d) DOE S/CI website which utilizes these sources and is located at: http://tis.eh.doe.gov/paa/sci/.

(6) Identifying the management position responsible for these activities and serving as a point of contact with the Office of Environment, Safety and Health.

b. Work Process Controls. Work processes must be developed and implemented using available S/CI information, and must include the following elements.

(1) Engineering involvement in the development of procurement specifications; during inspection and testing; and when replacing, maintaining, or modifying equipment.

(2) Procurement processes that prevent introduction of S/CIs by—

(a) identifying technical and QA requirements in procurement specifications;

(b) accepting only those items that comply with the procurement specifications, including consensus standards, and commonly accepted industry practices; and,

(c) inspecting inventory and storage areas to identify, control, and disposition S/CIs.

(3) Inspection, identification, evaluation, and disposition of S/CIs installed in all safety applications and other applications that create potential hazards. (Safety applications are those whose failure could adversely affect the environment, safety, or health of the public or workers. This term includes "safety systems" in nuclear facilities as defined by 10 CFR 830.2);

(4) Engineering evaluations and disposition of S/CIs installed in safety applications/systems or in applications that create potential hazards must consider potential risks to the public and worker and cost/benefit impact and include a schedule for replacement (if required).

(5) Ensuring that S/CIs identified in non-safety applications during routine maintenance and/or inspection are reported, evaluated, and dispositioned to prevent future use in safety applications.

(6) Contacting the DOE Inspector General (IG) before destroying or disposing of S/CIs and their documentation to determine whether to retain them for criminal investigation or litigation.

(7) Testing procured or installed S/CIs as necessary using approved engineering test methods.

(8) Reporting S/CIs to responsible program offices; the Office of Environment, Safety and Health; and the IG in accordance with DOE O 231.1A, *Environment, Safety, and Health Reporting*, dated 8-19-03, and DOE O 221.1, *Reporting Fraud, Waste, and Abuse*, dated 3-22-01.

(9) Conducting trend analysis and issuing lessons learned for use in improving the S/CI prevention.

SUPPECT/COUNTERFEIT ITEMS PREVENTION

1. DOE-WIDE SUSPECT/COUNTERFEIT ITEMS (S/CI) PREVENTION PROCESS. A DOE-wide S/CI prevention process is operated by the DOE Office of Environment, Safety and Health as a service to DOE and its contractors, and provides for—

   a. collection, analysis, and dissemination of S/CI information;

   b. notification of Secretarial Officers (SOs) when specific actions must be taken to investigate and resolve S/CI quality and safety issues; and,

   c. tracking and reporting the status of corrective actions.

   Note: This service does not relieve organizations from complying with the following requirements for the scope of their work.

2. SUPPLEMENTAL QUALITY MANAGEMENT SYSTEM REQUIREMENTS FOR S/CIs. A suspect/counterfeit items (S/CI) prevention process must be developed and implemented as a part of the organization's QAP commensurate with the facility/activity hazards and mission impact. The QAP must be applied to identifying and analyzing SC/Is, removing them, and preventing SC/Is from being supplied to DOE/NNSA and its contractors. The QAP must address the following elements for S/CI prevention:

   a. preventing the introduction and use of S/CIs through engineering involvement, design, procurement, testing, inspection, maintenance, evaluation, disposition, reporting, trend analysis, and lessons learned work process controls;

   b. training and informing managers, supervisors, and workers on S/CI processes and controls (including prevention, detection, and disposition of S/CIs);

   c. identifying and disposing of S/CIs on site;

   d. permitting the use an S/CI only when it has been found acceptable through engineering analysis and formal disposition process;

   e. collecting, maintaining, disseminating, and using the most accurate, up-to-date information on S/CIs and associated suppliers using all available sources including—

      (1) Government Industry Data Exchange Program,

      (2) Institute of Nuclear Power Operators, and

      (3) the DOE Occurrence Reporting and Processing System, and

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(4) the DOE S/CI website which utilizes the above sources and is located at: http://tis.eh.doe.gov/paa/sci/.

f. Identifying the management position responsible for these activities and serving as a point of contact with the Office of Environment, Safety and Health.

3. WORK PROCESS CONTROLS. Work processes must be developed and implemented using available S/CI information, and must include the following elements.

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a. Engineering involvement in the development of procurement specifications; during inspection and testing; and when replacing, maintaining, or modifying equipment.

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b. Procurement processes that prevent introduction of S/CIs by—

(1) identifying technical and QA requirements in procurement specifications;

(2) accepting only those items that comply with the procurement specifications, including consensus standards, and commonly accepted industry practices;

(3) inspecting inventory and storage areas to identify, control, and disposition S/CIs.

c. Inspection, identification, evaluation, and disposition of S/CIs installed in all safety applications and other applications that create potential hazards. (Safety applications are those whose failure could adversely affect the environment, safety, or health of the public or workers. This term includes "safety systems" in nuclear facilities as defined by 10 CFR 830.2);

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f. Contacting the DOE Inspector General (IG) before destroying or disposing of S/CIs and their documentation to determine whether to retain them for criminal investigation or litigation.

g. Testing procured or installed S/CIs as necessary using approved engineering test methods.

h. Reporting S/CIs to responsible program offices; the Office of Environment, Safety and Health; and the IG in accordance with DOE O 231.1A, *Environment, Safety, and Health Reporting*, dated 8-19-03, and DOE O 221.1, *Reporting Fraud, Waste, and Abuse*, dated 3-22-01.

i. Conducting trend analysis and issuing lessons learned for use in improving the S/CI prevention.

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CORRECTIVE ACTION MANAGEMENT PROGRAM

1. OBJECTIVE. To prescribe process requirements and responsibilities for DOE line managers to effectively perform corrective actions that resolve safety issues arising from:

   a. Findings—as identified by the Office of Independent Oversight and Performance Assurance Environment, Safety, and Health and Emergency Management (DOE O 470.2B, *Independent Oversight and Performance Assurance Program,* dated 10-31-02);

   b. Judgments of Need—as identified by Type A accident investigations (DOE O 225.1A, *Accident Investigations,* dated 11-26-97); or

2. c. Other sources as directed by the Secretary or Deputy Secretary.
2. REQUIREMENTS.

   a. Reporting Findings. The assessing organization listed in paragraph 1 submits the final assessment report within 10 calendar days of issuance to the:

      (1) applicable Field Element Manager(s) and Secretarial Officer(s); and,

      (2) Office of Environment, Safety and Health (ES&H) along with a synopsis of assessment report findings.

   b. Corrective Action Plan (CAP) Development, Approval, and Review.

      (1) Development of the CAP. The Field Element Manager (FEM), in consultation with the appropriate Secretarial Officer (SO), must prepare a single written, comprehensive CAP to address all of the findings contained in the assessment report, including both field and Headquarters corrective actions to resolve each finding, as appropriate. Additional guidance for preparing the CAP is outlined in Appendix G of DOE G 450.4-1B, *Integrated Safety Management System Guide*.

         (a) When findings and/or corrective actions to be addressed in the CAP apply to more than one SO, a lead SO must be appointed by mutual agreement or be appointed by the Deputy Secretary to coordinate and approve the CAP.

         (b) When findings and/or corrective actions to be addressed in the CAP involve multiple sites or organizations, to include DOE Headquarters policy organizations or other elements, the lead SO must designate a lead FEM as overall manager to coordinate and develop the CAP and track and report CAP data in the Corrective Action Tracking System (CATS) database.

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(c) Other responsible sites/organizations must forward their portions of the CAP to the designated lead FEM for consolidation and submission. Failure to provide this information will be brought to the attention of the lead SO for action.

(d) For each finding, the CAP must address the extent of conditions/causal factors that led to the finding, detailed description of corrective actions to resolve the finding, and a general outline for the conduct of the proposed independent corrective action effectiveness review outlined in paragraph 2d.

(e) For each corrective action the CAP must address a detailed description of the corrective action, date of initiation, corrective action deliverable that will signify completion, single responsible manager accountable for timeliness and effectiveness of the correction action, and planned completion date.

(2) Approval of the CAP. The CAP must be prepared on a schedule that will allow for review and approval by the SO or delegated designee within 60 calendar days from the date the transmittal forwarding the formal final assessment /investigation report was issued.

(a) The SO or designee must approve the CAP, including all proposed corrective actions from other responsible sites/organizations for each finding.

(b) When the proposed CAP cannot be submitted to the SO for approval within the required 60 days or the SO does not approve the proposed CAP, the FEM may formally request an extension from the SO as outlined in the DOE *CATS User's Guide*.

(3) Review of the CAP. The SO or designee must forward copies of the approved CAP to the organization that conducted the assessment for review and to the Office of ES&H.

(a) The organization that conducted the assessment must complete review of the approved CAP and provide results of the review and relevant comments to the SO and FEM within 30 calendar days from the date the transmittal forwarding the approved CAP was issued.

(b) The SO must evaluate comments from the organization that conducted the assessment and provide written response on how the comments will be addressed. If the SO decides to revise the CAP, the FEM must be notified to revise and resubmit the CAP for SO approval within a specified timeframe not to exceed 60 calendar days from the date the SO directed revision of the CAP. The

revised CAP must be submitted to the organization that conducted the assessment for review and a copy provided to the Office of ES&H.

(c) If there is disagreement concerning the CAP that cannot be resolved between the organization that conducted the assessment and the SO, it must be elevated through the organizational level of management hierarchy up to the Office of the Secretary, if necessary, for resolution.

c. Tracking and Reporting CAP Implementation.

(1) The FEM is responsible for implementing the approved CAP, and ensuring timely and effective completion of all corrective actions.

(2) The FEM must enter, track and report the status of the CAP and associated corrective actions to closure in the DOE CATS database (see Web site http://tis.doe.gov/portal/catsentry.html). Guidance for accessing and using CATS is outlined in the *DOE CATS User's Guide* and *CATS Data Dictionary* located on the Integrated Safety Management Corrective Action Management Program Web site (http://tis.eh.doe.gov/ism/cats.html).

(3) Upon SO approval of the CAP, the FEM must enter the remaining CAP data and corrective action data as stated in the approved CAP for each finding in CATS within 10 working days after approval. The FEM must ensure all corrective actions are tracked and their status reported to completion and verification. Completion of each corrective action must be annotated in the CATS "Descriptive Status" and "Completion Date" fields.

(4) Other sites/organizations who forwarded portions of the CAP and corrective actions to the lead FEM as stated in paragraph 2b(1)(c) must track and provide the FEM updates of their responsible portions of the CAP and corrective actions to completion and verification within the timeframes specified in this Order for the FEM.

(5) The FEM must update the status of the CAP in the CATS "CAP Status" field and the status of corrective actions in the CATS "Descriptive Status" field on a frequent basis (i.e. monthly), and begin each update with the date of input (i.e. 01/26/2004).

(6) Requests for CAP changes in CATS (i.e. planned corrective action completion date) must be approved by the SO who approved the CAP and submitted as outlined in the *CATS Users Guide*.

(7) Information in CATS will be used to provide periodic (e.g. quarterly) status reports to assist senior DOE management in monitoring the status of the CAMP.

d. Review of Corrective Action Effectiveness.

(1) Purpose of Corrective Action Effectiveness Reviews

(a) A thorough evaluation of identified findings and aggressive implementation of corrective actions outlined in the CAP should correct the underlying causes, but it may be determined that completed corrective actions have not effectively resolved or prevented recurrence of the same or similar findings. This result may be due to a variety of reasons (e.g. the revised procedure was published but not adequately promulgated or understood by the workers).

(b) Results of a follow-up effectiveness review of completed corrective actions will:

1 Determine whether completed corrective actions have effectively resolved and prevented recurrence of the same or similar findings at the performance level.

2 Identify additional actions necessary to effectively resolve the findings and prevent recurrence.

3 Collect corrective action effectiveness data for subsequent analyses and sharing of lessons learned.

(2) Conduct of Effectiveness Reviews.

(a) Upon completion of corrective actions for each finding, the FEM must initiate a follow up review to verify closure and determine corrective action effectiveness in assuring resolution of each finding and preventing recurrence. This review must be completed and formal review report approved by the FEM within 6 months after the CAP completion date (the date when all corrective actions for all findings listed in the CAP have been completed). NOTE: This requirement is effective on the approval date of this Order for all CAPs that have not been approved, CAPs that have been approved but are not complete (all corrective actions in the CAP are not complete and there is not a CAP Completion Date), and all future CAPs. The FEM will determine—

1 How the review is conducted

2 Who conducts the review

3 What specific completed corrective actions are reviewed for each finding

4 When the review is initiated

5 How the review report will be formatted

(b) Other sites/organizations that tracked and provided the FEM updates of their responsible corrective actions to completion and verification must coordinate effectiveness review activities with the lead FEM for consolidation and submission.

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(c) For each finding, the FEM will select for review a sufficient number of completed corrective actions to allow an objective, accurate assessment of effectiveness in resolving the finding and preventing recurrence. A 100 percent review of all corrective actions may not be necessary to determine effectiveness in resolving the finding.

(d) The FEM may initiate effectiveness reviews of selected corrective actions for each finding at any time during CAP implementation. Determination may be based on severity of a finding, length of time needed to review selected corrective actions, availability of resources to review corrective actions, and length of time before all corrective actions for the finding are to be completed.

(e) Effectiveness review participants may be comprised of Federal and/or contractor personnel and must be independent from the identified finding and those who developed and implemented the corrective actions.

(3) Types of Effectiveness Review Activities.

(a) There is a multitude of mechanisms available to line managers for determining the effectiveness of corrective actions in resolving each finding and preventing recurrence of the same or similar findings. They include documentation review, performance analysis, work observation/facility tours, performance testing, interviews, and trending of performance. Monitoring performance metrics based on operational data, tracking performance utilizing targeted assessments, and/or performing tailored scheduled assessments to gather the data can also be used to gather performance information.

(b) Which mechanisms or combination of mechanisms to use in the conduct of the effectiveness reviews will be determined by the FEM.

(4) Corrective Action Effectiveness Review Reporting and Follow Up.

(a) A formal report documenting the results of the effectiveness review must be completed and approved by the FEM no later than 6 months after the CAP completion date.

(b) If the FEM determines that additional time is required to successfully complete the effectiveness review, the "Effectiveness Review Approval Date" field in the CAP Data section of CATS must read, "See CAP Status" and an explanation concerning the status of the effectiveness review and revised completion date for the review must be entered into the "CAP Status" field in the CAP Data section of CATS.

(c) The report should include a cover page summary outlining overall scope, results, conclusions, rating and recommendations. A separate report form for each finding describing which corrective actions were reviewed, review activities and results, conclusions, rating (i.e. effective, partially effective, ineffective) and recommendations should be attached to the report cover page.

(d) FEM approval of the report must be recorded in the "Effectiveness Review Approval Date" field in the CAP Data section of CATS. A brief description of the Effectiveness Review results and follow up actions must be outlined in the "Effectiveness Review Results" field in the CAP Data section of CATS.

(e) Upon FEM approval, report recommendations must be implemented and followed up as directed by the FEM. The report and supporting documents should be maintained on file by the FEM.

(f) If the FEM revises the completed CAP based on report recommendations, the CAP revision with additional or revised corrective actions, as applicable, must be approved by the SO.

(g) Upon approval, CAP revisions must be entered into CATS and tracked to successful completion. Guidance for entering the revisions is outlined in the *CATS User's Guide*.

e. Lessons Learned.

(1) The FEM must develop and apply lessons learned identified from the assessment findings, corrective actions in response to the findings, and results of corrective action effectiveness reviews, as applicable. Implementation of lessons learned may occur at any time during the CAMP process.

(2) The FEM must evaluate identified lessons learned to determine if they may be applicable to the wider DOE community. If broader DOE applicability is determined, the lessons learned must be distributed to a select list of recipients through the DOE Lessons Learned Information Services Web site (http://tis.eh.doe.gov/ll).

f. Corrective Action Management (CAM) Team.

(1) The CAM Team, a cross-organizational working group of representatives from Headquarters and field offices, must be maintained to support and coordinate effective line management implementation of the CAMP.

(2) A charter outlining mission, functions, operations, membership, and leadership of the team must be maintained. The CAM Team is sponsored by the Office of Environment, Safety and Health and co chaired by a SO representative and the Office of Environment, Safety and Health.